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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,232	07/05/2001	Preeti Lal	PF 0525 USN	7102

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,232

Applicant(s)

Lal et al

Examiner

Fozia Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 10, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above, claim(s) 30, 33-35, and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-29, 31, 32, 36, and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Claims 1-20 have been canceled without prejudice or disclaimer and new claims 21-40 have been filed in the amendment filed on 03 December 2002, in Paper NO: 8. Thus claims 21-40 are pending.
2. Applicants' election with traverse of the invention of Group I (original claims 1-6, 9-15 and new claims 21-29, 31-32, 36-37), in Paper No. 8, filed on 03 December 2002 is acknowledged.

Applicants contend that it is unclear whether the polypeptide and the polynucleotide encoding it are "independent and distinct", inventions. This would appear to contravene Example 17, part 2 of Annex B of the Administrative Instruction Under PCT. Applicants' second ground of traversal is that the polypeptides of SEQ ID Nos: 1-9 and polynucleotides of SEQ ID Nos:10-18 are alternatives of a similar nature and should be examined in a single application. The polypeptides of SEQ ID Nos: 1-9 are identified as SOCS proteins on the basis of the presence of the characteristic "SOCS box", they share a common proper activity of being SOCS box proteins involved in cell signaling.

Firstly, the Examiner does not consider a polynucleotide and the encoded polypeptide as distinct and independent. As was set forth in the office action mailed on 29 October 2002, in Paper NO:7, if an international or a national stage application contains claims to multiple products, processes of manufacture or uses, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be

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considered as the main invention in the claims, see PCT Article 17(3)(a) and §1.476(c). In the instant application, the main invention comprises the first-recited product, to a purified polypeptide, the polynucleotide encoding it, an expression vector comprising said polynucleotide, a host cell comprising said vector and a method of producing said polypeptide. This is consistent with Example 17, Part 2 of Annex B. Instant case, claims multiple polynucleotide sequences and polypeptide sequences, which constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions.

Secondly, Applicants' traversal that the polypeptides of SEQ ID Nos: 1-9 and polynucleotides of SEQ ID Nos:10-18 are alternatives of a similar nature and should be examined in a single application is not found persuasive. Applicants assert that the polypeptides of SEQ ID Nos: 1-9 are identified as SOCS proteins on the basis of the presence of the characteristic "SOCS box", they share a common proper activity of being SOCS box proteins involved in cell signaling, however, currently, the state of the art is such that there is no common function or activity elucidated for all the proteins that contain an SOCS box. According to Rule 13.2, when the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled: (A) all alternatives have a common property or activity, and (B) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains. The polypeptides and the polynucleotides claimed in the instant application, do not have a common property or activity because the relationship between a function and "SOCS box" is not determined as yet. Therefore,

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in the instant application, the main invention comprises the first-recited product, to a purified polypeptide (SEQ ID NO:5), the polynucleotide encoding it (SEQ ID NO:14), an expression vector comprising said polynucleotide, a host cell comprising said vector and a method of producing said polypeptide.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 30, 33-35, 38-40 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Claim objections

3. Claims 21-29, 31-32 and 36-37 are objected to because of the following informalities:

Claims 21, 22, 25, 29, 31 and 37 recite non-elected sequences. Claims 23-24, 26-28, 32 and 36 are objected in so far as they depend on claims 21 and 31.

Specification

2a. It is noted that this application appears to claim subject matter disclosed in prior PCT Application No. PCT/US99/11497, now WO 99/61614, filed on 05/25/99. A reference to the prior application must be inserted as the first sentence of the specification of this application if Applicant intends to rely on the filing date of the prior application under 35 U.S.C. 120. See 37 CFR 1.78(a).

It is suggested that below the title of the invention be inserted:

Cross Reference to Related Applications

"This Application is a 371 of WO 99/61614".

Appropriate correction is required.

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2b. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).

An abstract on a separate sheet is required.

Claim Rejections - 35 U.S.C. § 101/112

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 21-29, 31-32 and 36-37 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 21-29, 31-32 and 36-37 of the instant invention are directed to an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 and the polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:14 which encodes said polypeptide. The specification describes the disclosed polypeptides being purified human SOCS proteins, (page 3, lines 20-30). Table 2 lists a number of signature sequences that the claimed polypeptides of SEQ ID NO:5 contains, and table 3 discloses that the polynucleotide of SEQ ID NO:14 is expressed in reproductive, cardiovascular and hematopoietic/immune system and that it is associated with cancer, inflammation and neurological disorders. However, the instant specification does not explain how the polynucleotide of SEQ ID NO:14 is associated with these diseases.

Instant specification states the claimed polypeptides contain SOCS box, however, it does not disclose any information regarding biological activity of the claimed polypeptide. Although instant specification asserts that claimed polypeptide can be used for diagnosis, treatment or prevention of

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cancer, immune and neurological disorders and infectious diseases, (page 15, lines 20-24), it does not disclose how is the claimed polypeptide and polynucleotide can be used in these disparate diseases.

Suppressor of cytokine signaling family (SOCS) are recently identified inhibitors of cytokine and growth factor signaling that act through Janus kinase (JAK)/signal transducers and activators of transcription pathway. One class of said family is composed of 8 proteins (CIS, SOCS-1 to SOCS-7), which contain a C-terminal SOCS box domain and a central SH2 domain. Other proteins the contain SOCS box contain WD-40 repeats, a SPRY domain or ankryn-repeat or GTPase domain N-terminal of the SOCS box, (see Hilton et al page 114, column 2 and figure 1). Thus it is unclear from the instant specification which group of SOCS box containing proteins does the claimed polypeptide belong to. It is thought that SOCS-1 plays an important role in regulating signal transduction by binding via its SH2 domain to activated JAK molecules and that CIS is thought to block STAT5. However, the roles that other members of this family play have not been elucidated. Although the conservation of the SOCS box at the amino acid level appears to be important, its function is not known at the moment, (see Hilton, page 118, bottom of column 1) and it seems that SOCS-1 does not act through the SOCS box to bind to JAK. Therefore, having an SOCS box does not impart a utility common to all proteins having this box.

Furthermore, without knowing the biological activity of the claimed polypeptide, what other domains does it contain, (for example does it contain an SH2 domain which seems important for SOCS-1, does the claimed protein regulate signal transduction and if so how?), one of ordinary skill in the art would not be able to use them or predict an activity for said protein, simply because it

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comprises an SOCS box. The claimed invention is not supported by either a substantially asserted utility, specific or a well established utility, because it is directed to polypeptide with no known activity.

4b. Claims 21-29, 31-32 and 36-37 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. No biological activity was assayed or determined for the claimed polypeptide or the polynucleotide encoding it. Therefore, there is no specific and substantial asserted utility or well established for the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5 or the polynucleotide of SEQ ID NO:14.

Should Applicants establish an activity for the polypeptide of SEQ ID NO: 5, instant specification would still fail to adequately describe and enable an isolated polypeptide comprising an amino acid that has at least 90% to the polypeptide of SEQ ID NO:5, or a biologically active fragment as recited in claim 21, or an isolated polynucleotide comprising at least 90% identical to the polynucleotide of SEQ ID NO:14. Applicants do not teach which regions of said polypeptide are critical for the functional integrity of the polypeptide, neither do they teach an isolated polynucleotide comprising at least 90% identical to the polynucleotide of SEQ ID NO:14 that encodes the desired polypeptide. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polypeptide having at least 90% sequence identity to SEQ ID NO:5, nor does the disclosure provide criteria that explicitly enable such critical features. With respect to "a biologically active fragment",

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limitation recited in claim 21, instant specification does not describe what biological activity is claimed, nor does it describe a fragment with any activity. The specification does not describe the structure of a fragment of the polypeptide of SEQ ID NO:5 that is active. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polypeptide, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

To practice the instant invention in a manner consistent with the breadth of claims 21 and 31, would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed polypeptide, which are required for functional and structural integrity of the claimed polypeptide or to determine all the possible polynucleotides comprising at least 90% identical to the polynucleotide of SEQ ID NO:14, which are encompassed by the claims. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a polypeptide which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5a. Claims 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites "...a biologically active fragment", however, it is unclear which biological activity is being referred to. Appropriate correction is required. Claims 22-29 are rejected under 35 U.S.C. 112, second paragraph in so far as they dependent on claim 21.

Conclusion

No claim is allowed.

Advisory Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
20 February 2003


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